IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OREXO AB and OREXO US, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 17-205 (CFC)
	)	
ACTAVIS ELIZABETH LLC,	)	
ACTAVIS PHARMA, INC.,	)	**REDACTED**
TEVA PHARMACEUTICALS USA, INC.,	)	**PUBLIC VERSION**
and TEVA PHARMACEUTICAL	)	
INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

OPENING BRIEF IN SUPPORT OF PLAINTIFFS' MOTION FOR A NEW TRIAL

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Pursuant to Fed. R. Civ. P. 59, Orexo moves for a new trial to address infringement, damages, and willful infringement of claim 2 of U.S. Patent 8,454,996 ("the '996 patent").

NATURE AND STAGE OF THE PROCEEDINGS

On March 25-28, 2019, the parties tried this case to a jury. The jury found that Defendants did not induce or contribute to infringement and therefore did not address damages or willful infringement. (D.I. 275). The Court entered judgment for Defendants. (D.I. 279).

SUMMARY OF THE ARGUMENT

When a court or counsel commits an error, "a new trial ***must be granted unless*** 'it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights.'" *Arthrocare Corp. v. Smith & Nephew, Inc.*, 310 F. Supp. 2d 638, 666–67 (D. Del. 2004), *aff'd in part and vacated in part*, 406 F.3d 1365 (Fed. Cir. 2005) (alterations in original) (emphasis added). Here, the Court erred when excluding two groups of evidence.

First, the Court improperly excluded evidence relating to a prior action where a Delaware court held that Actavis's generic Zubsolv—[redacted]—infringed the same patent at issue here. (*See* pp. 3-10). This Court's broad ruling excluded not only the prior court's final determination, but any reference to the Zubsolv action. (*See id.*). Evidence that Actavis defended infringement allegations against the same patent at issue here for its [redacted] generic Zubsolv and was found to infringe goes to the heart of the knowledge/intent element of indirect (induced and contributory) infringement.

The Court improperly balanced, under Fed. R. Evid. 403, the necessity of this highly probative and essential evidence against a presumed prejudicial impact to Defendants. (*See* pp. 4-7). And, the Court's determination of supposed prejudice included the assumption of a negative impact on Defendants' invalidity defenses. (*See* pp. 7-8). But Defendants withdrew

their invalidity defenses on the first day of trial. (*See id.*). Even so, the Court declined to revisit its determination and denied Orexo's request to submit an offer of proof. (*See id.*). Accordingly, the Court's balancing was flawed, and the exclusion was an error and an abuse of discretion.

The exclusion of the prior litigation prevented the jury from assessing critical facts—namely, that Defendants knew their [redacted] product was alleged and adjudicated by a court to infringe the '996 patent. (*See* pp. 3-10). And, Defendants compounded the detrimental impact of this exclusion by imploring the jury to find no intent (or knowledge of infringement) based on the alleged absence of that same excluded evidence. (*See* pp. 8-10).

Second, the Court erroneously excluded evidence related to Orexo's public disclosures (other than the '996 patent). (*See* pp. 10-15). These publications and Defendants' potential knowledge of them directly rebut Defendants' arguments that they could not have known that the accused products infringed the '996 patent and that they developed the accused products prior to the patent. (*See id.*). This evidence is probative of Defendants' knowledge and willful blindness of infringement and its exclusion substantially prejudiced Orexo. (*See id.*).

Due to these errors, the jury was asked to decide the issue of intent on a factual record that bore little resemblance to the uncontroverted history of Actavis's awareness of the patent claims and the infringement of its [redacted] generic Zubsolv. Accordingly, the Court should grant a new trial on infringement, damages, and willfulness.

LEGAL STANDARD

The Court may grant a new trial "for any of the reasons for which new trials have [] been granted in actions at law in the courts of the United States." Fed. R. Civ. P. 59(a). "[U]nlike the standard for determining judgment as a matter of law, the court need not view the evidence in the

light most favorable to the verdict winner" when considering a motion for a new trial. *Asahi Glass Co. v. Guardian Indus. Corp.*, 886 F. Supp. 2d 369, 379 (D. Del. 2012).

When a motion for a new trial is based on an alleged error, the Court must determine: "(1) whether an error was in fact committed, and (2) whether that error was so prejudicial that denial of a new trial would be 'inconsistent with substantial justice.'" *Arthrocare*, 310 F. Supp. 2d at 666. With respect to the second prong, "if including the improperly excluded testimony ***makes it more likely that the jury would have reached a different decision***, the error is not harmless" and ***a new trial should be granted***. *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 787 (3d Cir. 1996) (emphasis added). "***[A] new trial must be granted unless*** 'it is highly probable that [the erroneous ruling] did not affect the [objecting party's] substantial rights." *Arthrocare*, 310 F. Supp. 2d at 667 (alterations in original) (emphasis added). In other words, the Court need not determine that the jury would have reached a different conclusion, but only that the improperly excluded evidence would make a different conclusion more likely.

ARGUMENT

I. A NEW TRIAL SHOULD BE GRANTED ON INFRINGEMENT

Orexo's ability to present an indirect (induced and contributory) infringement case at trial was significantly prejudiced by the Court's exclusion of evidence addressing Defendants' knowledge and willful blindness of infringement. Orexo was precluded from presenting evidence relating to: (1) the Zubsolv action and (2) Orexo's publicly available disclosures.

A. The Court Erred in Excluding the Zubsolv Action and Infringement Decision

At the March 11, 2019 final pretrial conference, the Court granted Defendants' motion *in limine* to exclude evidence relating to the Zubsolv action. (*See*, *e.g.*, Ex. A, Pretrial Tr. at 74:2-76:15, 83:15-84:17). This ruling and related balancing analysis was in error for two independent reasons: (1) the Court's Rule 403 analysis did not properly weigh the necessity and highly

probative nature of this evidence against any prejudice to Defendants, and (2) the Court's ruling was largely based on the alleged prejudice to Defendants' invalidity case even though Defendants dropped their invalidity claims on the eve of trial.

1. The Court did not afford appropriate weight to the highly probative Zubsolv action, and thus its exclusion was an abuse of discretion

On Defendants' motion (D.I. 256 at D's MIL 1), the Court precluded evidence relating to the parties' prior Zubsolv action under Rule 403. (*See* Ex. A, Pretrial Tr. at 74:2-25, 83:15-84:17). The exclusion was largely based on the Court's determination that the risk of prejudice and confusion to Defendants' invalidity case outweighed its probative value. (*See id.*). While the Court agreed that the Zubsolv action was probative of "willfulness, knowledge, [and] intent", the Court's analysis did not consider the substantial impact that exclusion of this highly probative evidence would have on Orexo's indirect infringement case. (*Id.* at 83:15-17).

Actavis's development of its generic Zubsolv by the same scientists who developed the accused products, using the same technology, and subsequent litigation is highly probative of Actavis's knowledge of infringement. (*See supra* AOE[1], ¶¶ 1-9). Evidence that Actavis faced prior allegations relating to its generic Zubsolv—which Actavis knew was based on the accused products—and that this product was adjudicated to infringe, is highly probative that Defendants possessed knowledge of the details of the '996 patent and that Defendants had knowledge of infringement or willfully blinded themselves to infringement by the accused products.[2] (*See id.*).

The Zubsolv action is particularly probative given the court's findings relating to [redacted] and the '996 patent disclosures relating to bioadhesives. (*See id.* ¶¶ 5-9). The Zubsolv

[1] "AOE" refers to Orexo non-limiting addendum of evidence which appears on pages 18 to 20.
[2] In the Zubsolv action, Actavis analyzed whether its generic Zubsolv [redacted] infringed the '996 patent and failed to assert a non-infringement position in it notice letter. (*See supra* AOE, ¶¶ 2, 5, 6, 8). This also evidences Defendants' knowledge and willful blindness to infringement.

court found that Defendants' [redacted] process was evidence that buprenorphine was adhered to carrier particles as required by '996 patent. (*See id.* ¶ 7). Thus, Defendants' knowledge of the Zubsolv decision directly contradicts their argument that Actavis could not have known that [redacted] active to adhere to carrier particles in the accused products. (*Cf.* Ex. B, (3/26) Trial Tr. at 532:8-16, 578:25-580:2 (Yarasani), (3/28) Trial Tr. at 1006:4-1007:13 (D's counsel)). And, the '996 patent example 9[3] and related figures show that crospovidone and Ac-Di-Sol were disclosed ***together*** as exemplary bioadhesives: "cross-linked polyvinylpyrrolidone and croscarmellose sodium (Ac-Di-Sol®) were used as disintegrant and bioadhesive components . . . ." (Ex. C, JTX-1 at 10:48-12:16, Fig. 2; *see* Ex. B, (3/26) Trial Tr. at 305:16-307:21, 371:6-372:8, 382:3-383:7 (Mathiowitz)). Given the patent's interchangeable use of Ac-Di-Sol and crospovidone as bioadhesives, Defendants' acknowledgment in the Zubsolv action that Ac-Di-Sol met the bioadhesive limitation (*see supra* AOE, ¶ 9) refutes Defendants' argument that Actavis could not have known that crospovidone also met the bioadhesive limitation (*cf.* Ex. B, (3/28) Trial Tr. at 1000:4-1001:1, 1005:7-1006:4 (D's counsel)). Importantly, whereas at trial, Actavis relied on a lack of evidence that it understood the disclosure of the '996 patent, the uncontroverted facts demonstrate that Actavis analyzed the '996 patent in the context of the Zubsolv action. (*See id.* at 1005:19-1007:13; *supra* AOE, ¶ 2).

Thus, evidence relating to the Zubsolv action goes to the heart of Orexo's indirect infringement case and is strong evidence that Defendants possessed knowledge of or were willfully blind to infringement by the accused products. *See Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1318 (Fed. Cir. 2009) ("Circumstantial evidence is not only sufficient, but

[3] Example 9 discloses four formulations of the invention, some that use Ac-Di-Sol as a bioadhesive and others that use crospovidone as a bioadhesive: "***Formulation A has only ac-di-sol*** . . . ***Formulation B, C and D have only crospovidone***." (Ex. B, (3/26) Trial Tr. at 306:16-24 (Mathiowitz); *see* Ex. C, JTX-1 at 10:58-60, 11:1-13, 12:7-8, 2:57-60).

may also be more certain, satisfying and persuasive than direct evidence."). At a minimum, this evidence supports an inference that Defendants knew of or were willfully blind to infringement since they took no steps to investigate or avoid it, despite their knowledge of infringement by a [redacted] product and their familiarity with the '996 patent—none of which the jury was permitted to hear. (*See* Ex. B, (3/26) Trial Tr. at 531:8-533:1, 544:22-545:21, 579:7-580:2 (Yarasani).

This evidence is more probative of Defendants' knowledge of infringement than any potential prejudice or confusion and should have been admitted. The Third Circuit has held: "[T]here is a ***strong presumption that relevant evidence should be admitted*** and thus for exclusion under Rule 403 to be justified, the ***probative value of the evidence must be 'substantially outweighed' by the problems in admitting it***." *Lannett Co. v. KV Pharm. Co.*, No. CV 08-338-JJF, 2009 WL 10657988, at *6 (D. Del. Mar. 9, 2009) (emphasis added) (citing *Coleman v. Home Depot, Inc.* 306 F.3d 1333, 1343-44 (3d Cir. 2002)). Here, this evidence would have been presented to show Defendants' state of mind, not direct infringement by the accused products, and the Court could have mitigated any potential minimal prejudice or confusion by offering an instruction to the jury. Because the probative value ***was not*** "substantially outweighed" by prejudice or confusion, the Court's exclusion of this evidence was an abuse of discretion. *See Lannett*, 2009 WL 10657988, at *6 ("[T]he Court has discretion to exclude evidence only if it is 'substantially outweighed' by the dangers identified in Rule 403."). Indeed, that the Court itself expressed concerns as to whether Orexo had sufficient evidence of knowledge of or willful blindness to infringement to survive a Fed. R. Civ. P. 50(a) motion shows that the exclusion of evidence highly relevant to such issues could not be justifiable due to purported prejudice or confusion. (*See* Ex. B, (3/27) Trial Tr. at 666:23-669:19).

2. The Court's exclusion was based largely on the dismissed invalidity allegations, was clearly erroneous, and warrants a new trial

Also, when the Court balanced the probative value of the prior litigation versus the prejudicial impact under Rule 403, it gave serious weight to the risk of prejudice and confusion to Defendants' invalidity case:

> I've made the determination under Rule 403 that I think the admission of evidence related to Zubsolv litigation would confuse the jury. . . . ***There were different theories of invalidity***. . . . It involved a different drug. ***So there was prior art not presented in that case that apparently will be in this case, and I think that therefore the degree of unfair prejudice is so significant that it would substantially outweigh the probative value*** that the evidence would have, especially since . . . there's no debate even that the patent was known to the defendants prior to the Zubsolv litigation. . . . ***[S]o I am going to grant the motion***.
>
> * * *
>
> ***You did not move to preclude issue preclusion on obviousness.*** You made it clear it was a single legal issue, ***which was whether invalidity is a single issue as a matter of law. I spent an awful lot of time analyzing that*** and the prior litigation in connection with it, and I have reached again my best judgment that when I weigh the equities called for by Rule 403, the evidence should not be able to come in. Ex. A, Pretrial Tr. at 74:2-25, 84:10-17).

But one week prior to trial Defendants dropped their obviousness and enablement challenges, and just two days (Friday evening) prior to trial, Defendants dropped their remaining invalidity theories. (*See* D.I. 263; D.I. 266). The Court entered stipulations dismissing invalidity on Monday morning, the first day of trial. (*See id.*). Defendants did so knowing full well the reasoning articulated by the Court in excluding evidence related to the Zubsolv action. The removal of invalidity from the case on the first day of trial rendered the Court's pretrial weighing of probative value versus prejudice, based largely on Defendants' invalidity defense, clearly erroneous. *See*, *e.g.*, *Highmark Inc. v. Allcare Health Management System, Inc.*, 572 U.S. 559, 563 n.2 (2014) ("***A district court would necessarily abuse its discretion if it based its ruling on*** an erroneous view of the law or on ***a clearly erroneous assessment of the evidence***."); *Romag Fasteners, Inc. v. Fossil, Inc.*, 866 F.3d 1330, 1334, 1336-38 (Fed. Cir. 2017) (same proposition).

At the end of the first trial day, Orexo raised this issue again and requested permission to submit an offer of proof, pursuant to Fed. R. of Evid. 103, to show why the Court should admit evidence relating to the prior Zubsolv action. (*See* Ex. B, (3/25) Trial Tr. at 273:18-276:14). The Court however denied Orexo's request to make an offer of proof and referred back to its previous balancing analysis, which was based in large part on consideration of Defendants' invalidity defense. (*See id.* at 275:21-276:14). The Court never balanced the probative value of evidence relating to the Zubsolv action in the case that was actually tried, which did not include invalidity defenses. (*See id.*). In short, by basing its exclusion ruling on clearly erroneous facts (the dismissed invalidity claims), the Court abused its discretion warranting a new trial.

3. Excluding evidence relating to the prior infringement case and decision was prejudicial and impacted Orexo's substantial rights

As addressed above (pp. 3-8), the Zubsolv decision is probative of Defendants' knowledge of or willful blindness of infringement. If the jury were presented with evidence showing that Defendants knew a product similar to and based on the accused products infringed the '996 patent "it would be more likely that the jury would have reached a different decision." (*Holbrook*, 80 F.3d at 787; *see* pp. 3-8). As a result, the Court must grant a new trial. (*See id.*; *see also Arthrocare*, 310 F. Supp. 2d at 667).

The exclusion of evidence here, is analogous to the improper exclusion in *Omega Patents, LLC v. CalAmp Corp.*, No. 2018-1309, 2019 WL 1510676 (Fed. Cir. Apr. 8, 2019). In *Omega*, the Federal Circuit found that the district court erroneously excluded testimony "relating to [defendant's] state of mind prior to the alleged acts of infringement." *Id.* at *11. The Court held that this exclusion "substantially prejudiced [defendant's] ability to present its defense for indirect infringement" and "deprived [defendant] of the opportunity to support its defense that there was no inducement because it reasonably believed it did not infringe the patents. . . ." *Id.* at

*8. Similarly, the exclusion of evidence that Actavis's [redacted] generic Zubsolv infringed, prejudiced Orexo's ability to demonstrate that Defendants knew of, or were willfully blind to, infringement of the '996 patent through the use of the accused products.

Defendants exacerbated the substantial prejudice to Orexo during closing arguments by repeatedly requesting the jury to find against Orexo because Orexo did not present the very evidence that this Court excluded:

- "What you miss, ***what plaintiffs have not provided in the evidence at any time***, but particularly after 2013, ***is any connection between Suboxone and the '996 patent***. There is nothing that shows that anybody at Actavis thought the '996 patent had anything to do with Suboxone." (Ex. B, (3/28) Trial Tr. at 1002:21-25 (emphasis added)).

- "And so when we hear talk about after 2013 Actavis should have taken a look at the '996 patent, it's because Zubsolv and the Actavis product are different that they never would have done that, and they didn't do it. ***They did not know, there is no connection, no connection in the evidence that Actavis connected the product with the '996 patent***. (*Id.* at 1004:7-13 (emphasis added); *see also id.* at 1004:3-5).

- "But they have to prove that they had knowledge. ***They have not even proved that Dr. Yarasani even thought about the '996 patent in the context of the Suboxone and Subutex products***." (*Id.* at 1007:9-12 (emphasis added)).

- "Actavis continued through this whole time period ***without ever having any idea that the '996 had anything to do with Suboxone***, and Orexo didn't either. They fail on the intent element." (*Id.* at 1011:2-5 (emphasis added)).

[redacted] (*See supra* AOE, ¶¶ 1-9). [redacted] (*See* D.I. 14 at 1). And, in prior briefing, Actavis admitted that Actavis documents [redacted] (*Id.* at 11; *see supra* AOE, ¶ 1). Absent this evidence, Actavis's emphasis on the differences between branded Suboxone and Zubsolv

were deprived of context and provided the jury a misleading view of why Actavis would have been on notice that its generic Suboxone and Subutex infringed a patent that covered Zubsolv.

Again, the present situation is analogous to *Omega*, in which the Federal Circuit granted a new trial where evidence of intent was excluded and "***where [plaintiff] relied on the lack of such testimony in its closing arguments in support of willfulness***." 2019 WL 1510676, at *10 (emphasis added). Likewise, a Delaware court granted a new trial on indirect infringement where the exclusion of evidence limited plaintiff's ability to respond to defendant's argument:

> [T]he scope of [plaintiff's] trial presentation had been limited by the court's precluding testimony concerning [defendant's] pre-litigation response to infringement allegations regarding non-suit patents. In the end, ***[plaintiff's] hands were bound by the court's excluding evidence that was relevant to [defendant's] subjective belief of non-infringement, while [defendant's] overstepped the bounds*** of how [Defendant's fact witness's] testimony could be used regarding the issues of infringement and intent to infringe. *Intellectual Ventures I, LLC v. Canon Inc.*, the 104 F. Supp. 3d 629, 659 (D. Del. 2015) (emphasis added).

Thus, the substantial prejudice to Orexo's ability to present its case for indirect infringement due to the exclusion of this evidence, combined with Defendants' emphasis on the lack of evidence resulting directly from this exclusion, warrants a new trial.

B. The Court Erred in Excluding Orexo's Other Patent Disclosures

1. The Court's exclusion of evidence concerning Orexo's other public disclosures besides the '996 patent issuance was an error

On March 25, 2019, in response to Defendants' objection, the Court excluded the introduction of Orexo's patents and published patent applications (other than the '996 patent).[4] (*See* Ex. B, (3/25) Trial Tr. at 190:21-195:23). The Court determined that these publications were not relevant and could only become relevant if Orexo established that Actavis knew about a particular publication. (*See id.* at 193:8-195:23; Ex. B, (3/26) Trial Tr. at 387:18-25, 389:15-

[4] Throughout trial, the Court's ruling was broadened to exclude any mention of the '996 patent's 1998 invention date or the public availability of the underlying application(s). (*See* Ex. B, (3/26) Trial Tr. at 384:17-393:15, 399:20-402:5, 448:6-451:15).

392:5, 399:20-402:5, 448:6-451:15). This ruling was erroneous and left Orexo unable to respond to Defendants' arguments that they independently developed the accused products and could not have known that use of the accused products would infringe the '996 patent.

First, relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Evidence that Orexo publications as early as 2000 disclosed that dry mixing causes active to adhere to carrier particles in sublingual buprenorphine products and as early as 2006 disclosed that crospovidone as a bioadhesive in sublingual tablets unquestionably makes it more probable that Defendants knew of or were willfully blind to infringement upon learning of the '996 patent. (*See supra* AOE, ¶¶ 11-14).

These publicly available disclosures also would have provided evidence that rebutted Defendants' arguments. For example, Orexo's publications directly contradict D's counsel's improper and incorrect argument that Orexo did not know crospovidone was a bio/mucoadhesive until this lawsuit was filed. (*See* Ex. B, (3/28) Trial Tr. at 1008:15-18). Orexo's publications from at least 2006 explicitly disclose crospovidone as a preferred bioadhesive. (Ex. E, PTX-1253 at 9:13-17; *see supra* AOE, ¶ 14). And, the existence of Orexo's publications (made public prior to and during Actavis's development of the accused products) that disclose crospovidone as a bioadhesive in sublingual tablets and that dry mixing leads to adherence between active and carrier particles, contradicts Defendants' arguments of that they could not have known by 2013 that the accused products infringed the '996 patent. (*See supra* AOE at ¶¶ 11-14; Ex. B, (3/28) Trial Tr. at 999:1-14 ("[Actavis] made the product ***before*** the patent even existed") (emphasis added), *see id.* at 1000:21-1002:12 ("***[Actavis] did not have any possible knowledge that they were using this in a way that could be infringing***.") (emphasis added)). The existence of these

publications also discredits the testimony of Actavis's formulator that he does not believe that dry mixing leads to adherence (*see* Ex. B, (3/26) Trial Tr. at 579:7-25 (Yarasani)) and that he would only consider crospovidone a disintegrant, not a bioadhesive (*see id.* at 544:22-545:10). In short, this evidence is highly probative.

In addition, Defendants' practice of performing literature searches and gathering information about other companies' products, including Orexo's, shows the importance of these publications to determining the understanding in the art regarding. (*See id.* at 518:1-10 (Yarasani), (3/27) Trial Tr. at 683:11-684:22 (Jones)). Actavis's formulator admitted that he performed searches when developing the accused products—when Orexo's publications were available. He also found and reviewed an Orexo patent application while searching for technical information in 2013. (*See* Ex. B, (3/26) Trial Tr. at 518:1-10, 522:11-524:15 (Yarasani)). This Orexo patent application expressly cites numerous other published Orexo applications which disclose important '996 patent claim elements—such as dry mixing causing active to adhere to carrier particles and crospovidone as a bioadhesive. (*See* Ex. D, PTX-1347 at p. 10, [0017] (citing WO00/16751, WO 2006/103418, and WO 2008/068471); *supra* AOE, ¶¶ 11, 14).

Thus, a reasonable jury presented with Actavis's search history (including an Orexo-specific search in 2013) and evidence of the availability of numerous Orexo's public disclosures relating to crospovidone and dry mixing (*see supra* AOE at ¶¶ 10-14) could have reasonably concluded that Actavis had access to Orexo's disclosures and either knew of or willfully blinded themselves to infringement upon reviewing the '996 patent and its claims.

The relevance of the excluded information is analogous to that in *Suprema, Inc. v. International Trade Commission*, 626 F. App'x 273, 280-82 (Fed. Cir. 2015). There, the Federal Circuit found that the ITC's finding of willful blindness of infringement was supported by

substantial evidence where the infringer engaged in searches of its competitors, found related patents, and studied a related patent which incorporated the application for the patent in suit:

> The Commission observed that, Suprema developed the accused products, it ***admitted to engaging in extensive market research on its competitors***. Suprema also ***admitted to researching and identifying Cross Match's patents***, including the '993 and '562 patents. ***Suprema specifically studied the '562 patent, which incorporates by reference*** in four portions of its specification the patent application . . . ***that led to the '344 patent***. . . . The Commission noted that, because the '562 and '344 patents ***have overlapping inventors and share the same assignee, Cross Match, "a word search likely would have identified both patents."*** *Id.* at 280-81 (emphasis added).

Similarly here, Orexo publications disclosed key facts which bear on Defendants' knowledge and willful blindness of infringement. Given Defendants' practice of performing searches and their admitted awareness of an Orexo application and the '996 patent, a reasonable jury presented with numerous public Orexo's disclosures could infer that a sophisticated company like Actavis/Teva at best would have been willfully blind to avoid learning whether crospovidone was a bioadhesive or dry-mixing led to adherence in its products. (*See id.* at 280-81; Ex. B, (3/26) Trial Tr. at 531:8-533:1, 544:22-545:21, 579:7-580:2 (stating Actavis failed to investigate infringement after obtaining the '996 patent).

Thus, evidence that Orexo had widely publicized its technology and done so as of the time Actavis developed the accused products was both relevant and more probative of Actavis's knowledge of and willful blindness to infringement than any potential prejudice or jury confusion. (*See supra* AOE, ¶¶ 10-14). This evidence was excluded in error.

Second, the Court's requirement that Orexo prove actual knowledge of these publications (*see* pp. 10-11) was legal error because knowledge of infringement may be shown through willful blindness, and circumstantial evidence is sufficient to show infringement. *See*, *e.g.*, *Glob.-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 770 (2011); *Lucent*, 580 F.3d at 1318.

Orexo should not have been required to establish actual knowledge of these applications prior to eliciting further relevant testimony. Like the plaintiff in *Suprema*, Orexo presented evidence that Defendants performed searches (including an Orexo specific search in 2013) and that they found at least one Orexo publication. (*See Suprema*, 626 F. App'x at 280-82 (holding this evidence was sufficient to support indirect infringement); pp. 12-13). Based on this, a reasonable juror presented with Orexo's numerous publications could infer that Actavis would have found Orexo's other publications and upon learning of the '996 patent, knew that the accused products infringed or was willfully blind to that infringement. *See*, *e.g.*, *id.* ("The Commission noted that, because the [related] patents have ***overlapping inventors and share the same assignee***, Cross Match, ***'a word search likely would have identified both patents.***'. . ."") (emphasis added).

2. Excluding evidence relating to Orexo's other publications was prejudicial and impacted Orexo's substantial rights

As addressed above (pp. 10-14), evidence of Orexo publications bear on the issue of Defendants' knowledge of or willful blindness to infringement and if presented to the jury would have "***ma[de] it more likely that the jury would have reached a different decision***" than a scenario in which the jury had no understanding that Orexo had repeatedly made its technology public. *Holbrook*, 80 F.3d at 787. And, the exclusion of this evidence substantially prejudiced Orexo's ability to demonstrate that Defendants knew or were willfully blind to infringement of the '996 patent by the accused products. *See*, *e.g., Omega*, 2019 WL 1510676, at *8, *11.

Prejudice to Orexo was once again aggravated by Defendants' arguments that they developed the accused products prior to the patent and could not have known their products contained the features claimed in the '996 patent. (*See* pp. 10-12; Ex. B, (3/28) Trial Tr. at 999:1-14, 1000:21-1001:1, 1001:24-1002:12). But again, the public availability of Orexo's disclosures and Defendants' practice of performing searches (including an Orexo-specific search

in 2013) contradict Defendants' arguments that they could not have known that the accused products infringed the '996 patent. (*See supra* AOE at ¶¶ 10-14). And, exclusion of this evidence prejudiced Orexo's ability to respond to Defendants' incorrect arguments. (*See Omega*, 2019 WL 1510676, at *10 (granting a new trial based on the improper exclusion of evidence of intent and where the excluded party was left unable to respond to arguments raised by the other party); *Intellectual Ventures*, 104 F. Supp. 3d at 659 (same); pp. 10-12). Thus, the exclusion of this evidence substantially prejudiced Orexo's ability to present its case for indirect infringement and the Court here should grant a new trial.

C. The Court's Evidentiary Rulings Were Particularly Prejudicial in View of the Strength of Orexo's Direct Infringement Proofs

The Court's erroneous exclusion of key evidence, highly probative of Actavis's state of mind, that likely impacted the jury's verdict warrants a new trial, and was not simply harmless error. (*See Holbrook*, 80 F.3d at 787; pp. 3-15). While not required for entitlement to a new trial, the Court's evidentiary exclusions were particularly harmful here because the accused products met the elements of '996 patent claim 2.[5]

The evidence clearly shows that the accused products contain an effective amount ("an amount that elicits a therapeutic response") of buprenorphine adhered to substantially larger carrier particles. (Ex. B, at (3/26) Trial Tr. at 455:16-22 (Davies)). Orexo's experts showed that buprenorphine from 1 to 50 µm (~40% of buprenorphine in Actavis's Suboxone) was adhered to substantially larger carrier particles. (*See*, *e.g.*, *id.* (3/25) Trial Tr. at 245:24-247:23 (Bugay), (3/26) Trial Tr. at 456:4-457:24 (Davies)). Defendants' expert admitted that buprenorphine from 1 to 30 µm (~25% of buprenorphine in Actavis's Suboxone) was adhered to substantially larger carrier particles. (*See*, *e.g.*, *id.* (3/27) Trial Tr. at 852:3-14 (Omidian)). Thus, the only evidence

[5] Defendants did not contest, and accordingly admit, their knowledge of the '996 patent and that all claim limitations other than the "effective amount" and "bioadhesive" limitations were met.

addressing the comparative size of buprenorphine adhered to carrier particles was Orexo's and it indisputably showed that ***all*** of the adhered particles were substantially smaller than the carrier particles per the patent claim. (*Cf.* Ex. C, JTX-1 at 12:37-41).

Also, there was no dispute that, whether it was 25% or 40%[6], the amount of buprenorphine adhered in the accused products was an effective amount. First, 0.1 mg is indisputably disclosed as a therapeutically effective amount of buprenorphine in the literature and 0.26 mg is the effective amount of buprenorphine in Orexo's FDA approved, commercial 0.7 mg Zubsolv product. (*See* Ex. B, (3/26) Trial Tr. at 457:25-460:1, 513:1-514:3 (Davies); *cf. id.* (3/27) Trial Tr. at 859:4-863:8 (Weiss)). All of Actavis's products contain over 0.1 mg (the literature reported effective amount) and over 0.26 mg (the effective amount in Orexo's 0.7 mg Zubsolv) of buprenorphine adhered. Second, it was uncontested that the small buprenorphine particles contribute to the therapeutic effect and that only ~25% of the buprenorphine in brand Suboxone sublingual tablets is effective. (*See id.* (3/26) Trial Tr. at 461:13-463:24, 513:11-514:13 (Davies), (3/25) Trial Tr. at 246:14-22 (Bugay), (3/27) Trial Tr. at 861:1-22 (Weiss)). Given this undisputed evidence the "effective amount" limitation was met.

Similarly, the clear weight of the evidence at trial shows that Actavis's accused products contained a bioadhesive. (*See* Ex. C, JTX-1 at 12:42-43). The '996 patent expressly discloses that, in dry mixed sublingual tablets, crospovidone is a bioadhesive. (*See* p. 5). Based on this alone it was more likely than not that crospovidone was a bioadhesive in the accused products which are also dry mixed sublingual tablets—a very specific type of formulation of which few examples exist. (*See* Ex. B, (3/26) Trial Tr. at 381:10-17 (Mathiowitz)). But, Orexo's experts

[6] ***25%*** of the buprenorphine in the accused products equals ***0.5 mg and 2 mg*** respectively for the 2 mg and 8 mg dosage strengths. And ***40%*** of the buprenorphine in the accused products equals ***0.8 mg and 3.2 mg*** respectively for the 2 mg and 8 mg dosage strengths.

provided additional evidence, including literature that disclosed crospovidone as a bioadhesive in sublingual tablets, explaining the mechanism of how crospovidone works as a bioadhesive, and testing data. (*See*, *e.g.*, *id.* at 296:15-297:17, 300:17-305:4, 309:8-312:13, 320:18-330:19 (Mathiowitz)). This evidence plainly establishes that the bioadhesive limitation was met.

Given the strength of Orexo's other evidence, it is highly likely that the Court's exclusion of Orexo's evidence relating to knowledge of infringement tainted the jury's analysis and undermined its verdict. Thus, a new trial should be granted.

II. A NEW TRIAL SHOULD BE GRANTED ON WILLFULNESS AND DAMAGES

The jury did not reach the issue of damages or willful infringement and thus, for the same reasons discussed above, the Court should also grant a new trial on these issues. Independently, as addressed above, the Court erred in excluding evidence probative of Defendants' knowledge or willful blindness of infringement and prejudiced Orexo's ability to present its case and respond to Defendants' arguments. These errors also warrant a new trial on willfulness.

ADDENDUM OF EVIDENCE

Orexo presents the following non-limiting addendum ("AOE") of some of the evidence that it would have presented if not for the Court's evidentiary rulings.

The Zubsolv Action

1. [redacted] (Ex. F, PTX-1243 at 0020 (emphasis added); *see also id.* at 0001, 0055, 0064; D.I. 14 at 11 [redacted]) (emphasis added); Ex. B, (3/26) Trial Tr. at 444:11-13, 446:22-447:23 (P's counsel); D.I. 256 at Orexo's Opp. To D's MIL 1 at p. 1 & Ex. 1A at 108:6-13).

2. Prior to the Zubsolv action, Actavis analyzed whether its generic Zubsolv infringed three Orexo patents (including the '996 patent), and memorialized this analysis in a notice letter pursuant to the § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act dated May 16, 2014. (*See* Ex. G, Zubsolv Notice Letter at 1). In its notice letter, Actavis did not assert a non-infringement position related to the '996 patent for its generic Zubsolv product— [redacted] (*See id.* at Enclosure A, p. 10; AOE, ¶ 1).

3. On June 26, 2014, Actavis knew that Orexo filed an infringement action asserting that the use of Actavis's generic Zubsolv infringed Orexo's patents, including the '996 patent. *Orexo AB v. Actavis Elizabeth LLC*, No. CV 14-829 (SLR), at D.I. 1 (D. Del. June 26, 2014).

4. By November 15, 2016, Actavis knew that Actavis's generic Zubsolv was found to infringe the '996 patent and that the '996 patent was valid. *See Orexo AB v. Actavis Elizabeth LLC*, 217 F. Supp. 3d 756, 781 (D. Del. 2016).

5. [redacted] (Ex. F, PTX-1243 at 0056 (emphasis added)).

6. [redacted] (*See*, *e.g.*, *id.* at 0020, 0021, 0038, 0050-52, 0055, 0056, 0061, 0064; D.I. 14 at 11).

7. Actavis knew that the Zubsolv court found that Actavis's [redacted] process [redacted] was probative of whether the '996 patent claimed structure of an effective amount of buprenorphine adhered to larger carrier particles was present. *See Orexo*, 217 F. Supp. 3d at 781 ("Dr. Sinko testified that Actavis'

manufacturing process would yield an interactive mixture. . . .[F]or the reasons articulated above, the court finds that Orexo has proven . . . that Actavis' tablets infringe the asserted claims.").

8. [redacted]. (*See*, *e.g.*, Ex. F, PTX-1243 at 0048 ([redacted]; *id.* at 0021 [redacted]); Ex. H, PTX-1245A at 1 ([redacted]

9. In the Zubsolv action, Actavis did not contest that Ac-Di-Sol was a bioadhesive and thus accepted that an ingredient very similar to crospovidone was both a disintegrant and a bioadhesive. (*See*, *e.g.*, AOE, ¶ 8; *Orexo*, 217 F. Supp. 3d at 777).

Orexo's Other Publications

10. On September 24, 1998, Orexo filed the Swedish application that led to the '996 patent. (*See* Ex. C, JTX-1 at (30)). Thus Orexo's invention predated Actavis's development of the accused products (starting in 2007). (*See* Ex. B, (3/28) Trial Tr. at 998:17-24).

11. The PCT application that led to the '996 patent was filed on September 24, 1999 and was published and available for review by Actavis on March 30, 2000, prior to development of the accused products. (*See id.*; Ex. C, JTX-1 at (63); Ex. I, PTX-410 at (21), (43)). This application disclosed a sublingual formulation, buprenorphine, and that dry mixing will adhere active to carrier particles. (*See* Ex. I, PTX-410 at 1:5-7, 9:5-9, 10:4-6).

12. The PCT was processed into the USPTO on June 8, 2001, given serial no. 09/787,888, and issued on July 13, 2004 as U.S. Patent 6,761,910 ("the '910 patent"). (Ex. J,

PTX-205 at (21), (22), (45), (86), (87)). The'910 patent was available to the public prior to development of the accused products and share the same disclosure as the PCT. (*See id.*)

13. The '996 patent application, a continuation to the '910 patent, was filed on November 22, 2011, published on December 13, 2012, and granted on June 4, 2013. (*See* Ex. C, JTX-1 at (22), (65)). As a continuation, the '996 patent disclosure is substantially similar to the published PCT and the '910 patent. The '996 patent and publication also expressly discloses crospovidone as a bioadhesive in example 9 and the corresponding figures. (*See* Ex. C, JTX-1 at 10:49-12:8, Fig. 2; Ex. K, PTX-1248 at [0074-92], Fig 2).

14. Orexo has numerous other publications, which were available prior to or during Actavis's development of the accused products, and disclose crospovidone as a bioadhesive, sublingual tablets, buprenorphine, and that dry mixing will adhere active to carrier particles. (*See*, *e.g.*, Ex. E, PTX-1253 (pub. 10/5/06) at (43), 1:4-6, 5:1-2, 8:15-9:17, 13:15-18; Ex. L, PTX-1251 (pub. 6/12/08) at (43), 1:4-6, 5:23-24, 10:10-11:12, 15:31-16:3); Ex. M, PTX-1250 (pub. 5/27/10) at (43), [0001], [0022], [0039-41], [0064]).

CONCLUSION

For the above reasons, Orexo respectfully requests this Court grant a new trial.

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May 2, 2019

CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2019, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 9, 2019, upon the following in the manner indicated:

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